Richard A. Clark (State Bar No. 39558)
rclark@pmcos.com
Natasha N. Dawood (State Bar No. 228410)
ndawood@pmcos.com
Parker, Milliken, Clark,
O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
Telephone: (213) 683-6500
Facsimile: (213) 683-6669

Katharine R. Latimer (admitted *pro hac vice*)
klatimer@hollingsworthllp.com
Gregory S. Chernack (admitted *pro hac vice*)
gchernack@hollingsworthllp.com
Hollingsworth LLP
1350 I Street NW
Washington, DC 20005
Telephone: (202) 898-5800
Facsimile: (202) 682-1639

[Defendant's Additional Counsel Listed on Next Page]

Attorneys for Defendant NOVARTIS PHARMACEUTICALS CORPORATION

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ADRIANN GEORGES,

Plaintiff,

vs.

NOVARTIS PHARMACEUTICALS CORP., et al.

Defendants.

Case No. 2:06-cv-5207-SJO-VBK

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFF'S OMNIBUS MOTION IN LIMINE [NO. 1]

Hearing Date: November 27, 2012
Time: 9:00 a.m.
Courtroom: 1
Judge: Hon. S. James Otero

ADDITIONAL COUNSEL:

Joseph M. Price (*admitted pro hac vice*)
joseph.price@faegrebd.com
Faegre Baker Daniels LLP
2200 Wells Fargo Center
90 S. Seventh Street
Minneapolis, MN 55402-3901
Telephone: (612) 766-7000
Facsimile: (612) 766-1600

Regina M. Rodriguez (*admitted pro hac vice*)
regina.rodriguez@faegrebd.com
Faegre Baker Daniels LLP
1740 Walnut Street, Suite 300
Boulder, CO 80302-5335
Telephone: (303) 447-7700
Facsimile: (303) 447-7800

Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this memorandum in opposition to Plaintiff's Omnibus Motion *in Limine* [No. 1]. For the reasons identified below, the Court should deny plaintiff's motion.

A. Evidence of Plaintiff's Disability Insurance Is Relevant and Admissible, and Is Not Barred by the Collateral Source Rule.

In California, the collateral source rule "precludes deduction of compensation the plaintiff has received from sources independent of the tortfeasor from damages the plaintiff 'would otherwise collect from the tortfeasor.'" *Howell v. Hamilton Meats & Provisions*, 52 Cal. 4th 541, 548, 129 Cal. Rptr. 3d 325 (Cal. 2011); *see also Helfend v. Southern California Rapid Transit Dist.*, 2 Cal. 3d 1, 6, 84 Cal. Rptr. 173 (Cal. 1970) ("if an injured party receives some compensation for his injuries from a source wholly independent of the tortfeasor, such payment should not be deducted from the damages which the plaintiff would otherwise collect from the tortfeasor."). NPC acknowledges this rule and does not intend to present evidence of any collateral payments for such a purpose. However, the collateral source rule does not bar evidence of insurance for otherwise permissible purposes. For example, Ms. Georges contends in this case that she has been and is currently unable to work "[b]y large measure" because of her alleged development of ONJ. 6/28/12 Georges Dep. at 127:11-14 (**Ex. 1**). Evidence of Ms. Georges' disability insurance claims, through both Social Security Disability Insurance as well as any private disability insurance she may have had, is relevant to the credibility of this contention, as well as to the issues of *when* and *why* Ms. Georges was ultimately rendered unable to work. Specifically, while Ms. Georges contends in this lawsuit that she could not work because of her jaw problem, her disability insurance records tell a different story. *See* 6/28/12 Georges Dep. at 131:18-136:15 (discussing and authenticating Deposition Exhibit 18 as her Social Security Disability application); Deposition Exhibit 18 to 6/28/12 Georges Dep. at 4 (identifying "metastatic breast cancer" as the condition limiting her ability to work)

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

(**Ex. 2**). NPC's use of this evidence for this purpose at trial would not run afoul of the collateral source rule, and the Court should deny plaintiff's motion for this reason.

B. NPC Does Not Intend to Present Evidence or Argument that a Verdict for Plaintiff Will Adversely Impact Pharmaceutical Companies' Incentive or Ability to Develop New Medications.

NPC does not intend to present such evidence or argument to the jury, and therefore does not oppose Section (B) to plaintiff's Omnibus Motion *in Limine* [No. 1].

C. NPC Does Not Intend to Present Evidence or Argument that a Verdict for Plaintiff Will Impact the Cost of Medications, or the Ability of the Jury, Any Individual, or Any Industry to Access Medications.

NPC does not intend to present such evidence or argument to the jury, and therefore does not oppose Section (C) to plaintiff's Omnibus Motion *in Limine* [No. 1].

D. NPC Does Not Intend to Present Comments or Personal Anecdotes By Lawyers or Witnesses About Themselves or Family Members Who Have Used Aredia® or Zometa®.

NPC does not intend to present such evidence or argument to the jury, and therefore does not oppose Section (D) to plaintiff's Omnibus Motion *in Limine* [No. 1].

E. NPC Does Not Intend to Use the Phrases "Litigation Crisis," "Lawsuit Crisis," or "Lawsuit Abuse."

NPC does not intend to use any of these three phrases, and therefore does not oppose Section (E) to plaintiff's Omnibus Motion *in Limine* [No. 1], at least with regard to the three phrases identified. NPC does not know what other phrases plaintiff contends are improper by moving to exclude "similar terms or phrases," and therefore opposes Section (E) with regard to any unidentified terms or phrases.

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

F. NPC Is Permitted to Present Evidence and Argument About Possible "Overwarning" and the Concern that Too Many Warnings Can Dilute the Effectiveness of Warnings Generally.

In Section (F) of plaintiff's motion, plaintiff seeks to preclude NPC from presenting evidence or argument that "state warning defect or failure-to-warn laws pressure drug manufacturers to add unsubstantiated, false, or invalid warnings in order to avoid lawsuits." Pf.'s Mem. at 5 (ECF No. 161-1). While NPC does not necessarily intend to pin any such blame on state tort laws, it does intend to present evidence and argument regarding the concept of "overwarning" in general and its consequences, primarily, diluting the effectiveness of other warnings generally.

As Judge Cogan recently held when denying a similar motion in the Hogan case, the issue of over-warning "goes to the heart of the case – whether the risk of developing ONJ was sufficiently high to warrant adding *yet another* warning to the label." *Hogan v. Novartis Pharms. Corp.*, No. 06-260, 2011 WL 1533467, *14 (E.D.N.Y. April 24, 2011) (emphasis added) (denying plaintiff's motion *in limine*); *see also Mahaney ex rel. Kyle v. Novartis Pharms. Corp.*, 835 F. Supp. 2d 299, 321 (W.D. Ky. 2011) (denying plaintiff's motion *in limine*, holding that "[o]verwarning, or warning fatigue, is a legitimate concern of manufacturers when creating labels for consumers."); *Winter ex rel. Baldwin v. Novartis Pharms. Corp.*, No. 06-4049, slip op. at 2 (W.D. Mo. March 8, 2012) ("*Winter* Order") (denying subsection (g) to plaintiff's motion *in limine*, which sought to exclude evidence and argument regarding the concept of overwarning); *Bessemer v. Novartis Pharms. Corp.*, No. MID-L-1835-08-MT, slip op. at 11 (N.J. Super. Ct. June 11, 2010) ("*Bessemer* Order") (denying plaintiff's motion *in limine* part (bb) to exclude evidence or argument "that too many warnings of serious injuries will dilute the effectiveness of warnings generally" so as not to prevent NPC "from arguing that its warning was reasonable in light of the available scientific evidence").

In this case, the adequacy of NPC's Aredia® and Zometa® labeling is one of

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

the central disputed issues. For example, plaintiff argues that NPC's warnings about ONJ were inadequate, but in NPC's view, the early anecdotal reports about this newly-discovered condition supported the language that was added in September 2003, to address post-marketing reports of ONJ occurring in Aredia® and Zometa® patients. NPC is entitled to present its full defense as to the adequacy of its warnings, including why it used the language that it used when amending the labeling in September 2003. That explanation necessarily includes the potential concern of information overload due to "overwarning," which is a well-recognized concern for pharmaceutical labeling. *See, e.g.*, *Mahaney*, 835 F. Supp. 2d at 321 ("Overwarning, or warning fatigue, is a legitimate concern of manufacturers when creating labels for consumers."); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) ("While it is important for a manufacturer to warn of potential side effects, it is equally important that it not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings.").

To the extent plaintiff's motion is intended to preclude NPC from referencing the concept of overwarning generally, such relief would impose unfair, inappropriate restrictions on NPC's ability to present its full defense as to the adequacy of its warnings. NPC's duty was to provide only warnings of risks that were "known or reasonably scientifically knowable at the time of distribution" – not every theoretical, conceivable risk. *See Brown v. Superior Court*, 44 Cal. 3d 1049, 1069, 245 Cal. Rptr. 412, 424 (Cal. 1988). Like the courts in *Hogan*, *Mahaney*, *Winter*, and *Bessemer*, this Court should reject plaintiff's argument on this issue.

G. NPC Is Permitted to Present Evidence and Argument About the Importance of Providing Only Scientifically Valid Warnings.

In Section (G) of plaintiff's motion, plaintiff seeks to preclude NPC from presenting evidence or argument that "state tort law undercuts the FDA's mission to

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

provide only scientifically valid warnings." Pf.'s Mem. at 6 (ECF No. 161-1). While NPC does not necessarily intend to pin any such blame on state tort laws, it does intend to present evidence and argument regarding the importance of providing only scientifically valid warnings in the label. Providing warnings that are speculative and not scientifically valid poses the same risks discussed above with regard to the concept of overwarning, namely, the risks of diluting the effectiveness of the warning label, and of deterring potentially beneficial uses of drugs by making them seem riskier than warranted. Accordingly, for the same reasons discussed above in Section (F), the Court should deny this motion.

H. Evidence that the FDA Has Not Sanctioned NPC Regarding Aredia® and Zometa® is Relevant and Admissible.

Plaintiff seeks to exclude any statement that the "absence of any evidence of FDA sanction is proof of full and timely compliance with FDA regulations." Pf.'s Mem. at 6-7 (ECF No. 161-1). NPC operates in a heavily-regulated industry and is not permitted to make prescription drugs available to the public without FDA-approval. FDA can issue sanctions where it has found that a manufacturer has not complied with appropriate regulations. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349, 121 S. Ct. 1012 (2001). Evidence that NPC was never the subject of FDA sanctions regarding Aredia® or Zometa® is relevant to whether NPC complied with the agency's regulations and therefore relevant to whether the warnings for Aredia® and Zometa® were adequate. See Fed. R. Evid. 401. Moreover, it is well established that compliance with FDA regulations is evidence of due care and may be considered by the jury in determining whether NPC acted reasonably. *See, e.g., Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 966 (N.D. Ill. 2001) ("Evidence of compliance with regulations is evidence, but not conclusive, of due care."); *Erony v. Alza Corp.*, No. 94-5413, 1996 WL 554612, *1 (S.D.N.Y. Sept. 30, 1996) ("[C]ompliance with the FDA's requests or directives may be considered, in conjunction with all the evidence, in determining whether

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

defendants acted reasonably.")

Despite its powers and ability to do so, FDA has never sanctioned NPC or found anything improper in NPC's handling of Aredia® or Zometa®. Such evidence and argument is relevant to plaintiff's claims and NPC defenses. A number of other courts have denied this motion. *See, e.g., Mahaney*, 835 F. Supp. 2d at 320-321("It is unjust to allow Plaintiff to allege violations of the FDA's regulatory framework, while at the same time prohibiting NPC from explaining the absence of formal violations."); *Winter* Order at 2 (denying subsection (d) to plaintiff's motion *in limine*). This Court should do the same.

I. NPC is Permitted to Present Evidence Concerning Ongoing Trials and Studies Involving Aredia® and Zometa®.

Plaintiff's motion to exclude any references to "current clinical trials or expansion of [Aredia® and Zometa®'s] indications," Pf.'s Mem. at 7-8, has been rejected by several other courts in this litigation and should similarly be rejected by this Court. See *Hogan*, 2011 WL 1533467 at *14; *Winter* Order at 2 (denying motion subpart (c)); *Bessemer* Order at 4, 12 (denying motion subpart (gg)); *Fussman v. Novartis Pharms. Corp.*, No. 06-149, slip op. at 5-6 (M.D.N.C. Oct. 29, 2010). Plaintiff's experts rely upon data from ongoing trials to reach their opinions. *See, e.g.*, 9/3/10 Wayne Ray Dep. at 71:11-21 (citing AZURE clinical trial) (**Ex. 3**). Such evidence is relevant to (1) an understanding of how Aredia® and Zometa® work; (2) any claim that Aredia® or Zometa® are defectively designed; (3) whether Aredia® and Zometa® can cause ONJ; and (4) allegations that NPC has failed to adequately test its products or respond to reports of ONJ.

Moreover, as discussed in NPC's concurrently filed Memorandum of Points and Authorities in Opposition to Plaintiff's Motion *in Limine* [No. 2], evidence of all benefits Ms. Georges may have received from Aredia® and Zometa® is relevant and admissible because, if NPC is found liable in this case, it is entitled to have plaintiff's damages award offset by any benefits Ms. Georges received from her

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500

Aredia® and Zometa® therapy. *See Turpin v. Sortini*, 31 Cal. 3d 220, 236-37, 182 Cal. Rptr. 337 (Cal. 1982) (tort damages "must be offset by the benefits incidentally conferred by the defendant's conduct 'to the interest of the plaintiff that was harmed.'"); *Maben v. Rankin*, 55 Cal. 2d 139, 144, 10 Cal. Rptr. 353 (Cal. 1961) ("In determining the damages suffered as a result of a tortious act, consideration may be given, where equitable, to the value of any special benefit conferred by that act to the interest which was harmed."); Restatement (Second) of Torts § 920 ("value of the benefit conferred is considered in mitigation of damages") & cmt. a ("If a surgeon has destroyed an organ of the body, it may be shown in mitigation that the operation improved other bodily functions.").[1] Any benefits that have been demonstrated in recent or ongoing clinical trials are benefits that Ms. Georges may have received – even if they were not known benefits at the time Ms. Georges was on Aredia® and Zometa® therapy. Accordingly, such evidence is relevant and admissible, and the Court should deny plaintiff's motion.

CONCLUSION

For the reasons stated above, the Court should deny plaintiff's Omnibus Motion *in Limine* [No. 1].

DATED: October 30, 2012

PARKER, MILLIKEN, CLARK, O'HARA & SAMUELIAN, APC

By: /s/ Natasha N. Dawood
RICHARD A. CLARK
NATASHA N. DAWOOD
Attorneys for Defendant
Novartis Pharmaceuticals Corporation

[1] *See also Heckert v. MacDonald*, 208 Cal. App. 3d 832, 839, 256 Cal. Rptr. 369 (Cal. Ct. App. 1989) ("the 'special benefit' doctrine reflects the basic compensatory theory underlying tort damages by restricting recovery to the harm actually incurred."); *Johnson v. Superior Court*, 101 Cal. App. 4th 869, 887, 124 Cal. Rptr. 2d 650 (Cal. Ct. App. 2002) ("Under [Restatement Second of Torts] section 920's benefit doctrine . . . such damages must be offset by the benefits incidentally conferred by the defendant's conduct 'to the interest of the plaintiff that was harmed.'") (*quoting Turpin*, 31 Cal. 3d at 236-37, 182 Cal. Rptr. 337).

Parker, Milliken, Clark, O'Hara & Samuelian, APC
555 S. Flower Street, 30th Floor
Los Angeles, CA 90071
(213) 683-6500